DISPOSABLE MEDICAL PPE

OVERVIEW OF US MEDICAL DEVICE REQUIREMENTS

US STATES COVID-19 EUAS

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WHEN YOU NEED TO BE SURE

SGS

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- Matt joined the CRS Hardlines group at SGS in 2010.
- He specializes in regulatory, industry requirements, and quality testing.
- Matt focus is on medical PPE, tools, environmental exposure, and accelerated aging.
- As a senior technical manager of Hardlines, Matt designs and manages NBE (National Brand Equivalency) and benchmark testing programs.
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WHEN YOU NEED TO BE SURE

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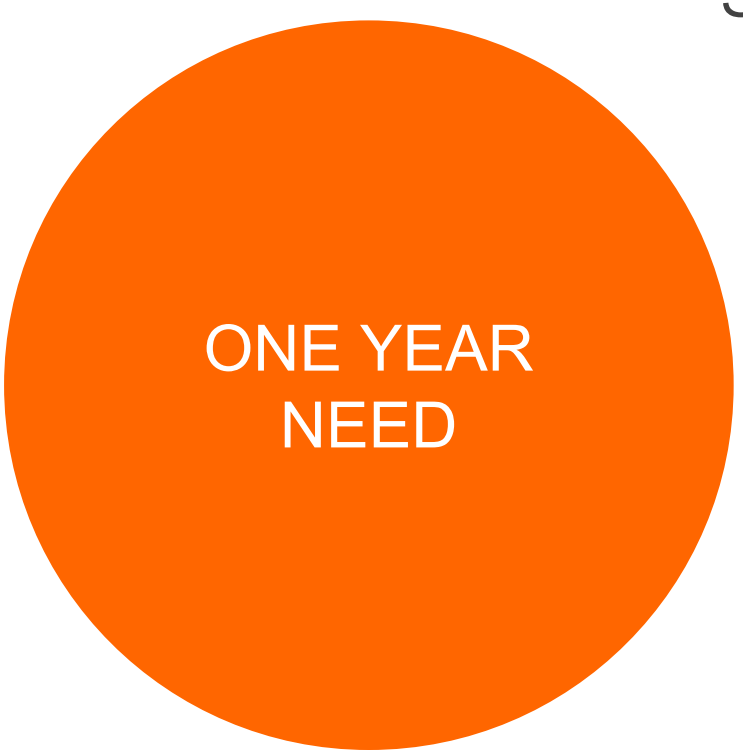
AGENDA

- Overview of Medical PPE Situation
- United States Medical Device Processes/Classes
- FDA's Response to COVID-19
- Product Specific Requirements
  - Medical Masks
  - Medical Gloves
  - Medical Gowns

SITUATION OVERVIEW

- Need RAPID expansion of supply base.
- Per Department of Health and Human Service
  - Just one year of pandemic 3.5 billion N95 respirators.
  - The Strategic National Stockpile 12 million N95 respirators and 20 million surgical masks.



Stockpile

DISPOSABLE MEDICAL PPE

Overview of US Medical Device Requirements

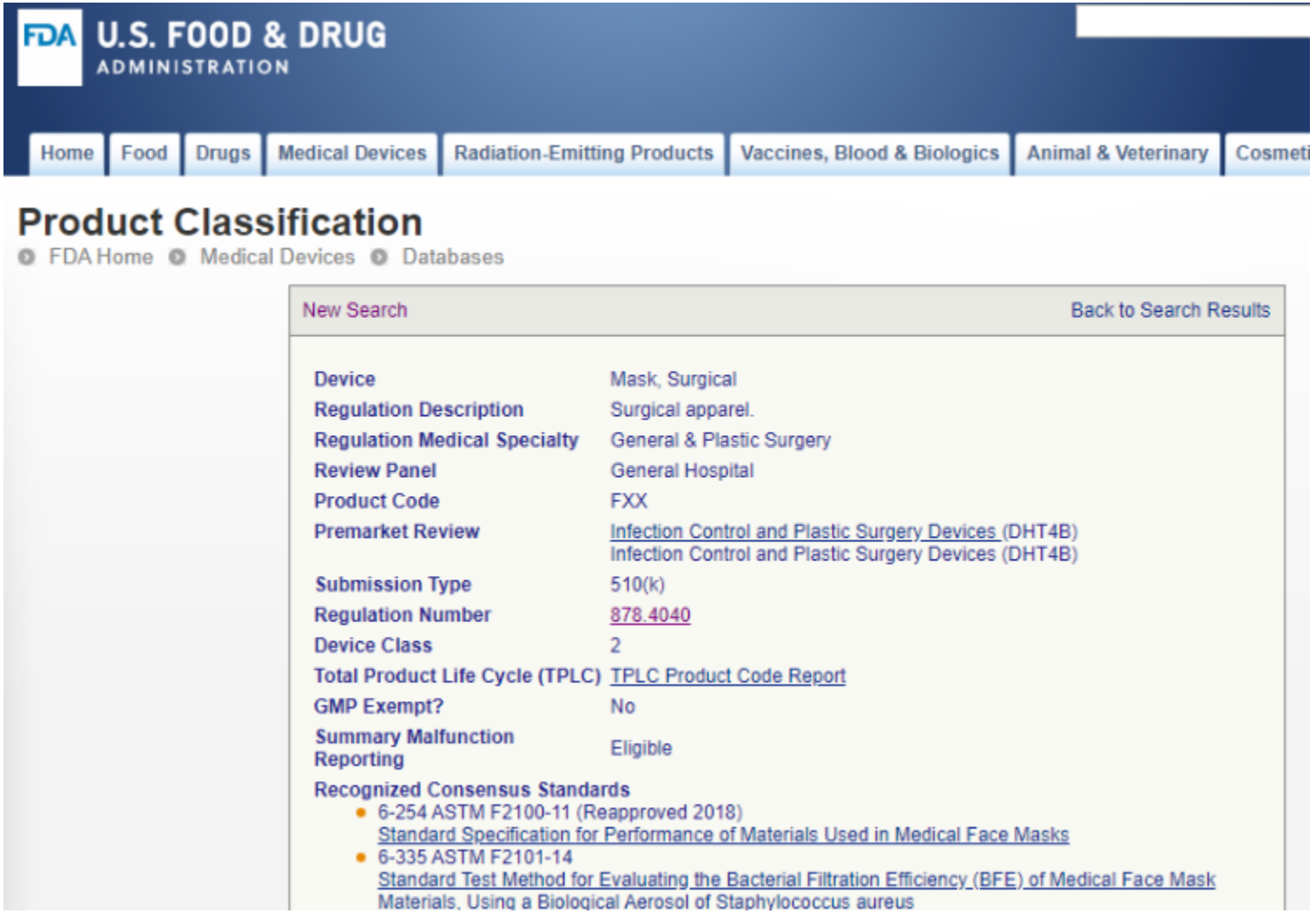
MEDICAL PPE – CLASSIFICATIONS

- FDA regulates the sale of medical device products in the U.S. and monitors the safety of all regulated medical products.
  - The Center for Devices and Radiological Health (CDRH) is the FDA center responsible for overseeing the medical device program.
- Each device is assigned to one of three risked-based regulatory classes: Class I, Class II or Class III.
  - Medical PPE largely fall within the Class I and Class II categories.

MEDICAL PPE – FDA PROCESS

- Determine FDA Product Code
- FDA assigns product codes (e.g. FXX) to a product type, these codes will determine
  - Applicable requirements
  - Device Class (e.g. Class II),
  - Recognized Consensus Standards (e.g. ASTM F2100).
- Submission Type (e.g. 510(k)),
  - Or Exemption
- Can be searched for online database
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

MEDICAL PPE – FDA PROCESS



FDA U.S. FOOD & DRUG ADMINISTRATION

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Product Classification

FDA Home › Medical Devices › Databases

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Device	Mask, Surgical
Regulation Description	Surgical apparel.
Regulation Medical Specialty	General & Plastic Surgery
Review Panel	General Hospital
Product Code	FXX
Premarket Review	Infection Control and Plastic Surgery Devices (DHT4B) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	878.4040
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 6-254 ASTM F2100-11 (Reapproved 2018)
  Standard Specification for Performance of Materials Used in Medical Face Masks
- 6-335 ASTM F2101-14
  Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

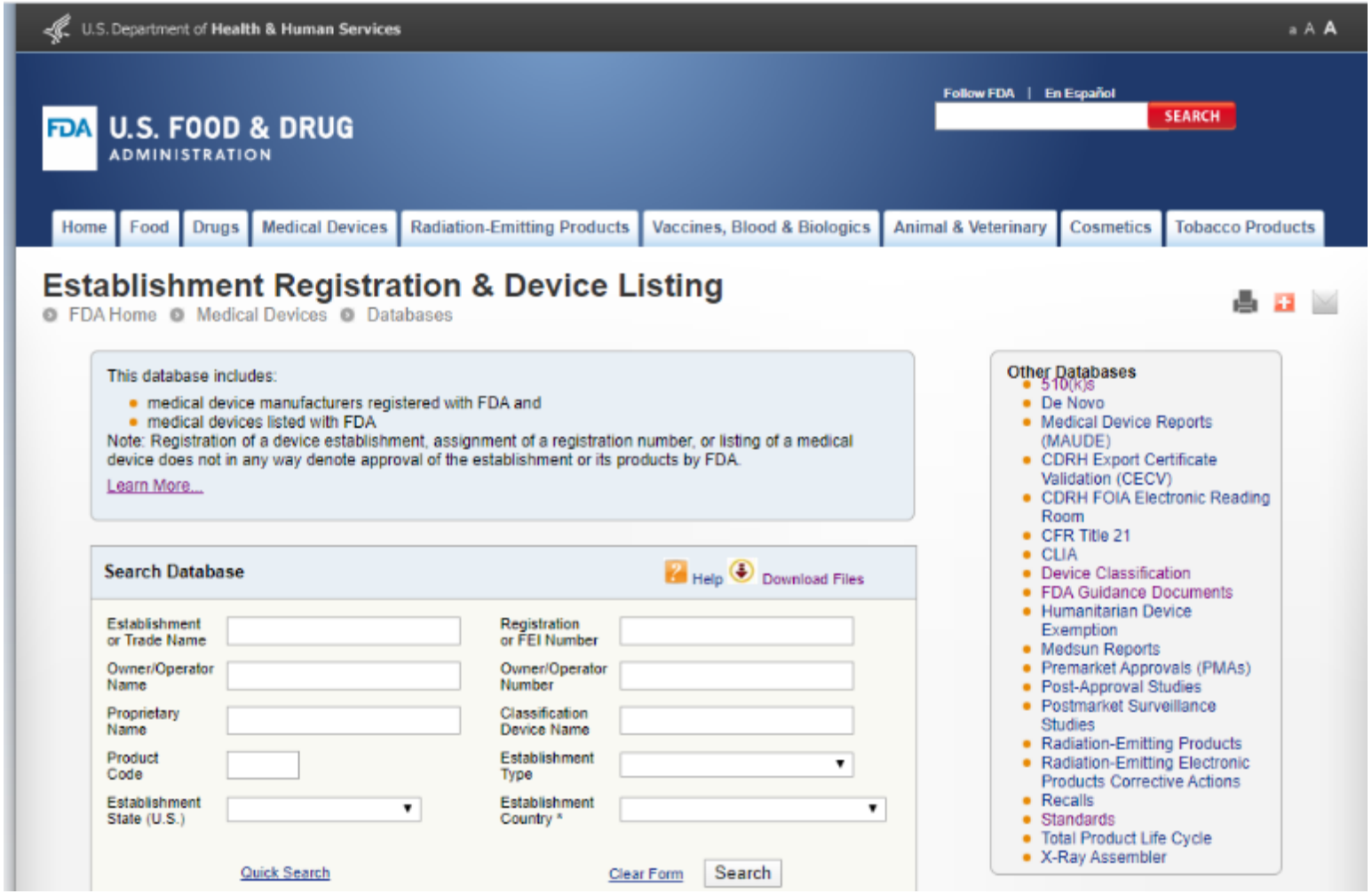
MEDICAL PPE – FDA PROCESS

- Premarket 510(k) premarket notification
  - Application submitted to FDA minimum 90 days in advance.
- Demonstrates to FDA the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device
- Standard medical PPE are “cleared medical” devices, which are devices that FDA determines substantially equivalent to (similar) another legally marketed device.
- 21 CFR Part 80
  - Establishment Registration
  - Medical Device Listing

MEDICAL PPE – FDA PROCESS

- Establishment Registration:
  - Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.)
- Medical Device Listing
  - Manufacturers must list their devices with the FDA. Establishments required to list their devices include:
- Required to register annually with the FDA.

MEDICAL PPE – FDA PROCESS



MEDICAL DEVICE – FDA PROCESS

Step	Class I	Class II
Classify Device	Lower risk, simple design,	Medium risk, more complex design
Manufacturing	Manufacture their devices in accordance with Good Manufacturing Practices	
Determine 510(k) Applicability	May or may not require 510(k) premarket notification	Likely requires 510(k) premarket submission, may have regulatory controls.
Prepare and Submit 510(k)	Must demonstrate that the new device is cleared as "substantially equivalent" to a predicate device in terms of intended use, technological characteristics, and performance testing, as needed.	
Meet Regulatory Controls	General Controls requirements (e.g. misbranding)	Special Controls (e.g. performance standard.
Registration and Listing	A device facility must register its establishment and list its devices with the FDA. Must wait until it receives FDA clearance or approval before registering and listing.	

MEDICAL DEVICE PROCESS – COVID-19

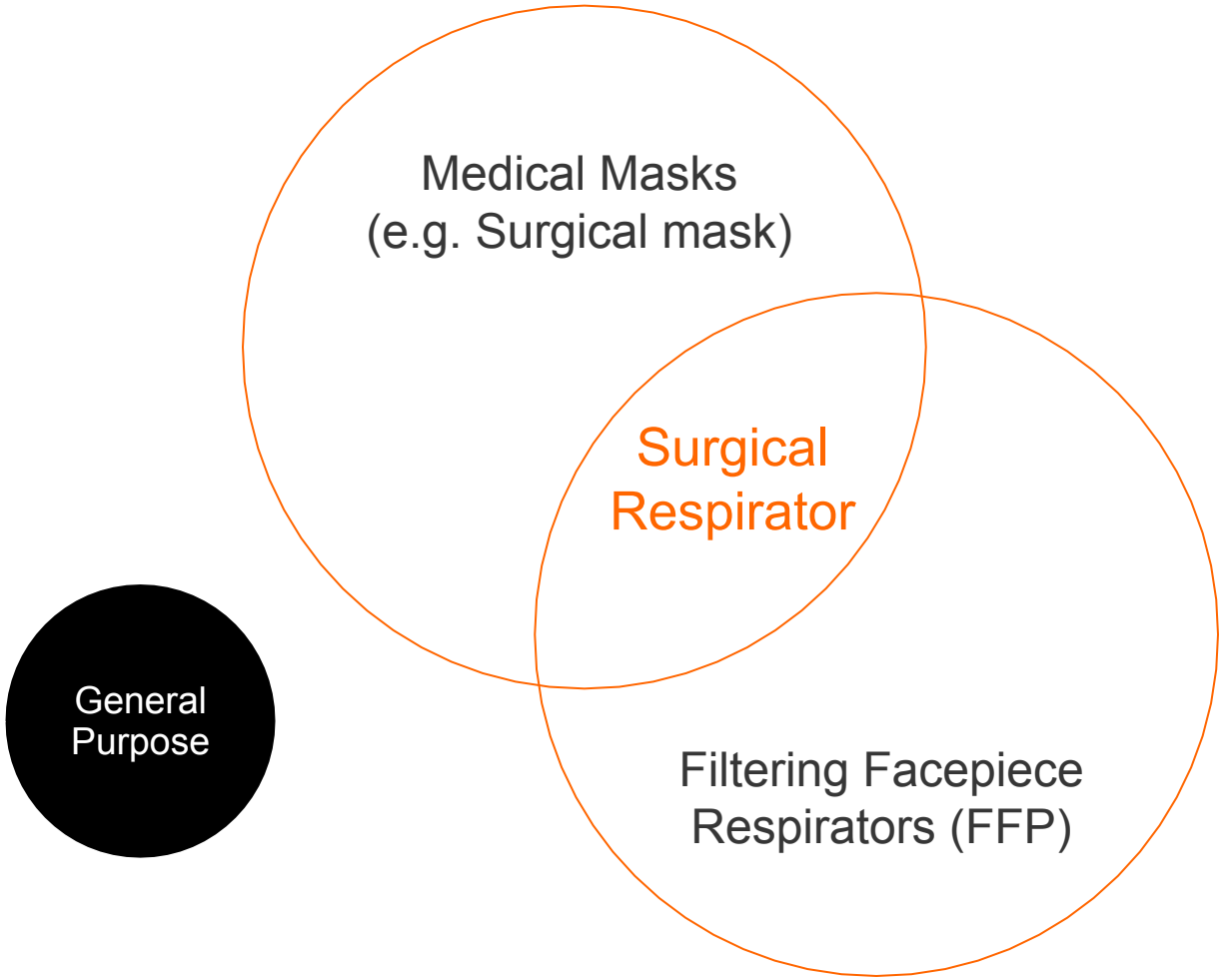
- FDA has released Emergency Use Authorizations (EUA's) to address medical PPE shortage during pandemic.
  - Easing/waiving some regulatory requirements of PPE.
  - https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations
- Allows unapproved medical products or unapproved uses of approved medical products in emergency when there are no adequate, approved, and available alternatives
  - Requires FDA review of performance, safety and labeling • Allows devices not FDA-cleared or approved to be marketed in the U.S.
  - Waives FDA cGMP and the quality system requirements, 21 CFR Part 820 (design, manufacture, packaging, labeling, storage, and distribution)
  - In effect for the duration of the national emergency

DISPOSABLE MEDICAL PPE - MASKS

Medical Masks and Respirators

- Applicable Medical Device Regulations
- Impact of COVID-19 EUA

TYPES OF DISPOSABLE FACIAL PROTECTION



GENERAL PURPOSE
FACE MASKS

Low | Medium | High

- User: General use
- Fit: Universal, loose fitting
- Protection:
  - Not intended for medical procedures or protection from a specific hazard.
  - Not intended for use to prevent disease or illness, and thus does not fall under scope of FDA.

PROCEDURAL/SURGICAL MASK REQUIREMENTS

Low | Medium | High

- Use/User: Single use, intended to provide providing healthcare services such as surgery and patient care.
- Protection: Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids.
  - Surgical masks are made in different thicknesses and with different ability to protect you from contact with liquids
  - Protects the patient from the wearer's respiratory emissions
- Fit: Ear looped (loose fitting), surgical masks may have ties for a tighter fit.

PROCEDURAL/SURGICAL MASK REQUIREMENTS

- General (non-surgical) medical face mask regulated under 21 CFR 878.4040 as “general surgical apparel”.
  - Class I Medical Devices
  - FDA product code LYU
  - 510(k) pre market notification Exempt
- Surgical masks are regulated under 21 CFR 878.4040.
  - Class II Medical Devices
  - FDA product code FXX
  - Requires 510(k) pre market notification
- “FDA has identified the risks to health generally associated with the use of the surgical masks
  - Contained in ASTM F2100 (FDA consensus standard)

PROCEDURAL/SURGICAL MASK REQUIREMENTS

- ASTM F2100: Standard Specification for Performance of Materials Used in Medical Face Masks
- Scope: Covers the minimum performance requirements for materials used in the construction of medical face masks.
- Use: US medical facemask industry standard, outlines test methods for classifying three levels of mask performance.

Characteristic	Cited Method	Level 1	Level 2	Level 3
Bacterial filtration efficiency, %	ASTM F2101	≥95	≥98	≥98
Differential pressure, mm H_2O/cm^2	EN 14683:2019, Annex C.	<5.0	<6.0	<6.0
Particulate filtration efficiency	ASTM F2299	≥85	≥98	≥98
Synthetic blood penetration resistance, minimum pressure in mm Hg	ASTM F1862	80	120	160
Flame Spread	16 CFR 1610	Class 1	Class 1	Class 1

N95 RESPIRATORS

Low | Medium | High

- Use/User: Single use, workers requiring advanced respiratory protection.
  - **N** = No Oil, **R** = Oil May Be Present, **P** = Oil is Present
- Two categories:
  - Industrial/Construction General N95
  - Healthcare Settings Surgical N95
- Protection: Protects against very small airborne particles (e.g. asbestos, bacteria)
- Fit: Tight seal around users mouth and nose
  - The proper seal of N95 filter media enables efficient filtration of at least 95 percent of very small (0.3 micron) test particles.

NIOSH APPROVAL

- CDC's NIOSH and OSHA regulate N95's
- Manufacturers must apply for NIOSH approval by submitting
  - performance tests,
  - drawings, packaging and label copy, detailed user instructions,
  - a product quality plan, and
  - a quality assurance manual for its manufacturing facility

SURGICAL N95

- N95s, single-use, disposable respiratory protective devices worn by healthcare workers during procedures
- Must meet FDA surgical mask standards
  - Tested for fluid resistance, BFE, PFE, flammability and biocompatibility
- Must meet NIOSH N95 requirements
  - Tested to N95 requirements

SURGICAL N95

- Distinction: Protect both doctor AND patient from the transfer of
  - microorganisms,
  - body fluids, and
  - particulate material
- Surgical N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH under 42 CFR Part 84.
  - Class II Medical Devices
  - FDA Product Code: MSH
  - Requires 501(k)

RECAP

	Surgical/Medical Mask	N95 Respirator	Surgical N95 Respirator
			
Regulator	Cleared by FDA (Code FXX)	Approved by NIOSH	NIOSH, FDA (Code MSH)
Intended Use and Purpose	Fluid resistant and protection against large droplets, splashes, or sprays of bodily or other hazardous fluids.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols)	Protect both the patient and health care personnel from the transfer of microorganisms, body fluids, and particulate material.
Face Seal Fit	Loose Fitting	Tight Fitting	
Respiratory Protection	Does not provide respiratory protection	Filters out at least 95% of airborne particles including large and small particles	
Leakage	Yes, around edges of mask.	If properly sealed/fit to face, no.	
Use	Disposable Single Use	Disposable Single Use (although can be re-used in emergencies)	

MEDICAL MASKS AND RESPIRATORS: EUA'S

- Enforcement Policy
  - https://www.fda.gov/media/136449/download
- EUA
  - https://www.fda.gov/media/137121/download
- EUA for Medical Masks FDA temporarily waives:
  - 501(k) Premarket Notification
  - Registration and Listing requirements in 21 CFR 807
  - Others…
- No claims regarding COVID-19
- Establishes two categories:
  - Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection
  - Surgical Masks Intended to Provide Liquid Barrier Protect

MEDICAL MASKS AND RESPIRATORS: EUA'S

- Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection (non-surgical masks).
- Cannot have labeling that misrepresents intended use
  - Accurately describe product as face mask, with body contact
  - Includes labeling against use in clinical setting
  - Doesn't have liquid protection claim, anti-microbial or anti-viral claims
  - The product is not labeled as a respiratory protective device, or use in high risk aerosol generating procedure.
- Can be used as "source control" to prevent spread of COVID-19.
  - Additional labeling requirements within EUA.

MEDICAL MASKS AND RESPIRATORS: EUA'S

- Surgical Masks Intended to Provide Liquid Barrier Protection, that:
- Physical Requirements:
  - Fluid Resistant per ASTM F1862
  - Passes 16 CFR 1610 Flammability
- Labeling Requirements:
  - Describe product as surgical mask, with body contacts
  - Cannot have labeling that increases undue risk such as:
    - uses for antimicrobial or antiviral protection or related uses or
    - uses for infection prevention or reduction or
    - related uses and does not include particulate filtration claims.
- Can contact the FDA through:
  - CDRH-COVID19-SurgicalMasks@fda.hhs.gov;

RESPIRATORS: EUA'S

- FDA does not intend to object to the distribution (including importation) and use of respirators (e.g. N95) identified in the CDC recommendations: Strategies for Optimizing the Supply of N95 Respirators
- Importers Note: For non-EUA products
  - Because the FDA cannot confirm the authenticity of these respirators, the
- FDA recommends that importers take appropriate steps to verify the authenticity of the products they import.
- Respirators from China need additional authorization.

RESPIRATORS: EUA'S

Country	Performance Standard	Guidance Documents	Primary Regulation	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3 P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3 PFF2	Fundacentro CDU 614.894	YES
China	GB 2626-2019	KN 100 KP100 KN95 KP95	GB/T 18664—2002	YES
Europe	EN 149-2001	FFP3 FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100 N99, P99, R99 N95, P95, R95	NOM-116	YES
US NIOSH Requirements	**NIOSH approved 42 CFR 84**	**N100, P100, R100 N99, P99, R99 N95, P95, R95**	**OSHA 29CFR1910.134**	**YES**

MEDICAL MASKS AND RESPIRATORS: EUA'S

- Seeking authorization, requests should include
  - General information
  - Product labeling
- Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number)
- Whether the device is manufactured in compliance with 21 CFR Part 820, ISO 13485 or an equivalent quality system
- Description of testing conducted on the device
- Send requests:
  - CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov

INTERNATIONAL STANDARDS

- EU Standards
  - BS EN 149: Respiratory protective devices. Filtering half masks to protect against particles
  - EN 14683: Medical face masks - Requirements and test methods
- GB Standards
  - GB 19083: Technical requirement for protective face mask for medical use
  - YY/T0969: Single use medical face mask
  - YY 0469: Surgical Masks

DISPOSABLE MEDICAL PPE - GOWNS

Surgical and Isolation Gowns

- Applicable Medical Device Regulations
- Impact of COVID-19 EUA

SURGICAL AND ISOLATION GOWNS

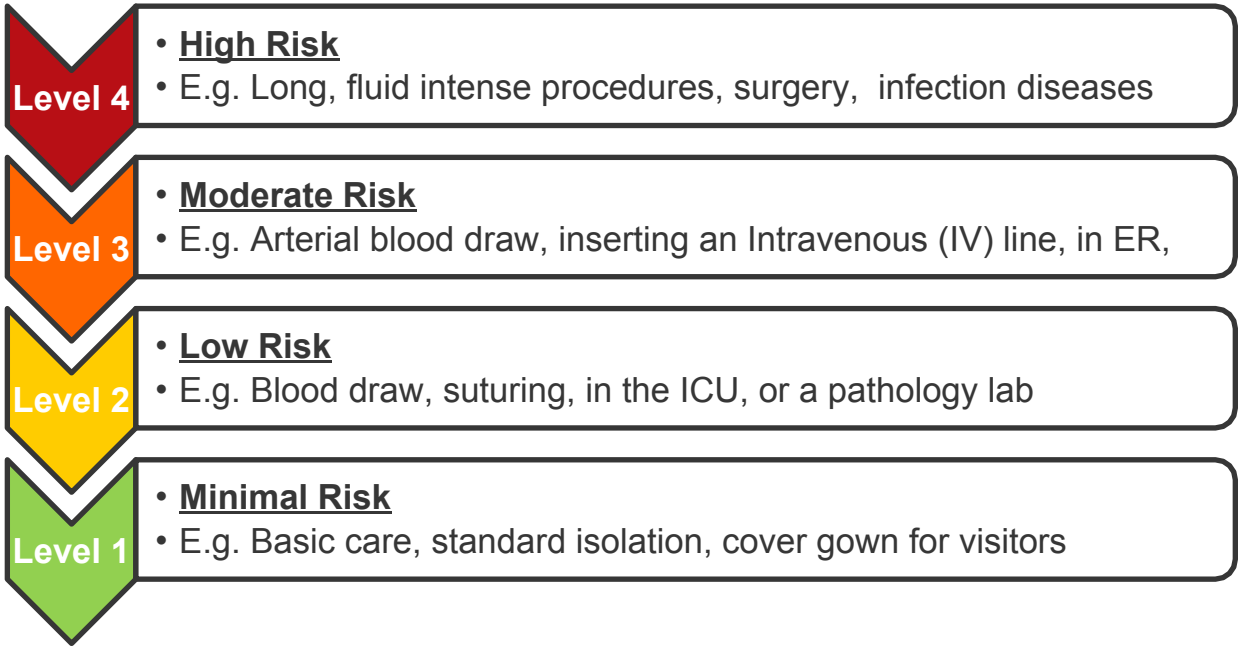
- Gowns: Personal protective garment intended to be worn to protect healthcare personnel, visitors, and patients. Regulated under 21 CFR 878.4040
- FDA Surgical gowns
  - Class II Medical Devices
  - FDA Product Code: FYA
  - Requires 510(k) pre market notification
- FDA Isolation gowns
  - Not intended for surgical procedures
  - Class I Medical Devices
  - FDA Product Code: OEA
  - May be exempt from 510(k) premarket notification

SURGICAL AND ISOLATION GOWNS

	Surgical Gowns	Isolation Gowns
		
Risk Level	Higher	Lower
Setting	Specifically used in operating rooms	Non-procedural Isolation Situations
Protects Against	Microorganisms, body fluids, and particulate matter	Microorganisms and body fluids
Industry Standard	AAMI PB70: Liquid Barrier Performance And Classification Of Protective Apparel And Drapes In Health Care Facilities	
ASTM Standard	ASTM F2407	ASTM F3352
FDA Classification	FDA Class II medical devices that require a 510(k) premarket notification.	FDA Class I

SURGICAL AND ISOLATION GOWNS

- Four levels of barrier properties for gowns are specified in AAMI PB70 and are included in ASTM standards.
  - AAMI PB70 □ Barrier performance
  - ASTM □ Physical Requirements



SURGICAL AND ISOLATION GOWNS: EUA'S

- The FDA does not intend to object to distribution and use (including importation) of the devices below without compliance with certain regulatory requirements, including
  - 510(k), registration and listing, and
  - quality system regulation requirements when the devices are tested and labeled consistent with the enforcement policy.
- Two gown categories:
  - Minimal-to-Low Barrier Protection
  - Moderate-to-High Barrier Protection
- Link: https://www.fda.gov/media/136540/download

SURGICAL AND ISOLATION GOWNS: EUA'S

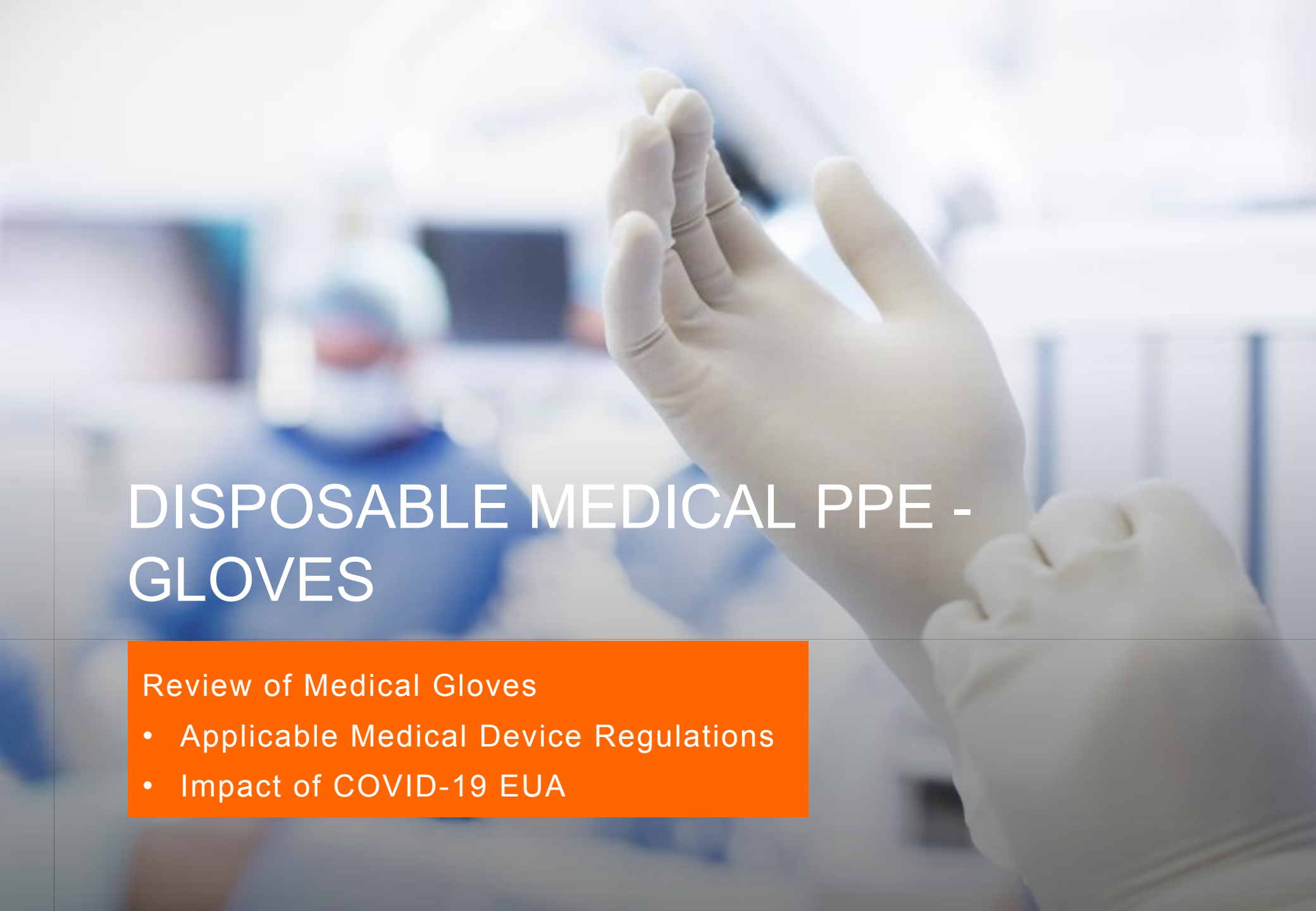
- Minimal-to-Low Barrier Protection (Level 1 or 2)
  - Shall meet labeling requirements that reduced risk of use where a Level 3 or 4 gown may be warranted
  - Cannot use word "surgical" or allude to use in surgical setting
  - No anti-microbial, or anti-viral protection claims.
- Classified as surgical gown if (increase requirements)
  - Labeled as such or is described as such in its labeling;
  - Has statements relating to moderate or high-level barrier protection; and/or
  - Has statements that it is intended to be sterile

SURGICAL AND ISOLATION GOWNS: EUA'S

- Moderate-to-High Barrier Protection (Level 3 or 4)
  - Meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70
  - Meets the Class I or Class II flammability standard per 16 CFR Part 1610; and
  - Has been demonstrated to be sterile if intended for use in surgical settings
- Includes general statements and makes recommendations that would sufficiently reduce the risk of use,
  - No infection prevention or reduction claims.
  - No anti-microbial or anti-viral claims.
  - Others…

INTERNATIONAL STANDARDS

- EU Standards
  - EN 14126: Performance requirements and tests methods for protective clothing against infective agents
- GB Standards
  - GB 19082: Technical requirements for single use protective clothing for medical use



DISPOSABLE MEDICAL PPE - GLOVES

Review of Medical Gloves

- Applicable Medical Device Regulations
- Impact of COVID-19 EUA

EXAMINATION AND SURGICAL GLOVES

- Examination Gloves: disposable personal protective equipment that are used to protect the wearer and/or the patient from the spread of infection or illness during medical procedures and examinations.
- Regulated under 21 CFR 880.6250, and 513(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act
  - Class I Medical Devices
  - Requires 510(k) pre market notification
- Other Glove FDA Product Codes:
  - Latex □ LYY
  - Vinyl (PVC) □ LYZ
  - Polymer (e.g. Nitrile, Polyurethane) □ LZA
  - Finger Cot □ LZB
  - Specialty (e.g. chemotherapy) □ LZC

EXAMINATION AND SURGICAL GLOVES

- Surgical Glove: a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
- Regulated under 21 CFR 880.4460, and 513(a)(1)(A) of the Federal Food, Drug, and Cosmetic Act
  - Class I Medical Devices
  - Requires 510(k) pre market notification
- FDA Product Codes KGO for all of the following
  - Surgeon's and Microsurgery Glove
  - Autopsy Surgeons Glove
  - Specialty/Chemotherapy/Radiation Surgeon's Glove

MEDICAL GLOVES

- ASTM has applicable standards depending on glove's function, type and protection level.
  - ASTM D3577 - Rubber Surgical Gloves
  - ASTM D3578 - Examination Gloves
  - ASTM D4679 - General Purpose (Household)
  - ASTM D5250 - PVC Gloves
  - ASTM D6319 - Nitrile Gloves
  - ASTM D6977 - Neoprene Gloves
  - ASTM D7103 - General Medical Gloves
  - ASTM D7329 - Food Prep and Handling
- Include requirements for size, tensile strength, freedom of holes etc.

MEDICAL GLOVES: FDA EUA'S

- Examination Gloves FDA temporarily waives:
  - 501(k) Premarket Notification
  - Registration and Listing requirements in 21 CFR 807
  - Others…
- Cannot create undue risk, thus must…
  - Product description as "unpowered glove"
    - Not "patient examination" or "surgeon" glove
  - Accurately labeled sterility status
  - Include list of body contacting materials
  - Not include material "free" claims (e.g. latex)
  - Not include claims that will create use in other settings
  - Others…

MEDICAL GLOVES: FDA EUA'S

- Surgeons Gloves FDA temporarily waives:
  - 501(k) Premarket Notification
  - Registration and Listing requirements in 21 CFR 807
  - Others…
- Cannot create undue risk, thus must…
  - Surgeon's gloves must meet ASTM D3577
  - Product description as "unpowered glove"
  - Accurately labeled sterility status
  - Include list of body contacting materials
  - Not include material "free" claims (e.g. latex)
  - Not include claims that will create use in other settings
  - Others…

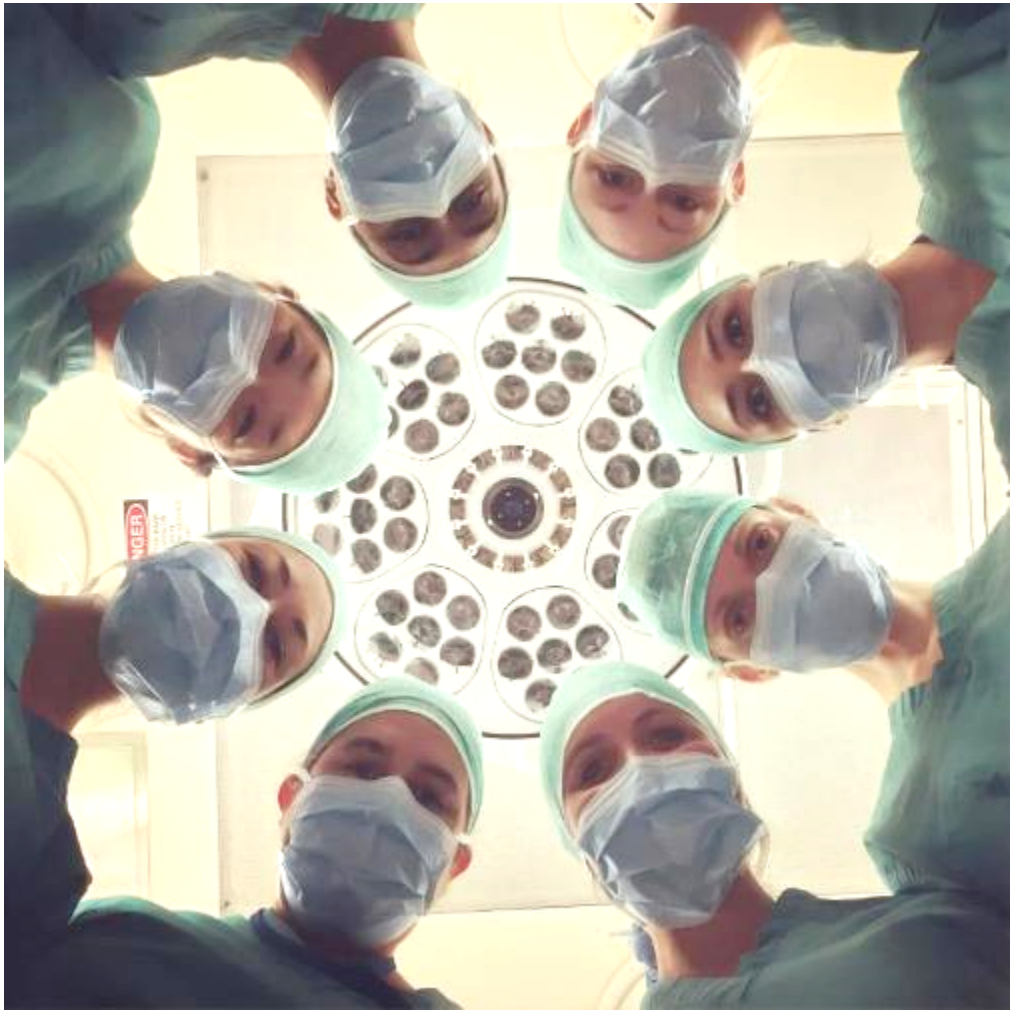
INTERNATIONAL STANDARDS

- EU Standards
  - EN 455-1: Medical gloves for single use. Part 1. Specification for freedom from holes
  - EN 455-2: Medical gloves for single use. Part 2. Specification for physical properties.
- ISO Standards
  - ISO 10282: Single-use surgical rubber gloves
  - ISO 11193: Single-use rubber examination gloves
- GB Standards
  - GB 7543: Single-use sterile rubber surgical gloves
  - GB 24786: Single-use non-sterile rubber surgical gloves
  - GB 24787: Single-use sterile PVC surgical gloves

DISPOSABLE MEDICAL PPE - CAPABILITIES

Contacts and Capability

QUESTIONS



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